DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Benjamin E. Maizel
President
Republic Drug Company
175 Great Arrow Avenue
Buffalo, New York 14207

November 29, 2000

Ref: NYK-2001-24

Dear Mr. Maizel:

During an inspection of your drug manufacturing facility located in Buffalo, New York, conducted between the dates of October 23 and October 27, 2000, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). Such deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act as follows:

1. Failure to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and drug products. The processes for the manufacturing of Lice Treatment Shampoo, pyrethrum extract 0.33% and piperonyl butoxide 4.00%, have not been validated [21 CFR 211.110(a)]. There is no specific validation protocol established. Equipment has not been qualified. There is no report of data establishing and supporting mixing speeds and times.

2. Failure to conduct a thorough and documented investigation into the failure of Licetrol 0.33% Medicated Shampoo, batch #M0194, to meet assay specifications requiring the batch to be reworked [21 CFR 211.192].

3. Failure to have individual inventory records for drug product containers and closures to allow determination of any batch or lot of drug product associated with their use [21 CFR 211.184(c)].

4. Failure to properly identify all production, filling equipment to indicate their contents [21 CFR 211.105(a)].

The above identification of violations and the observations on the FDA-483 issued at the end of the inspection are not intended to be an all-inclusive list of violations. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering award of contracts. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to Compliance Branch, Food and Drug Administration, New York District, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Laurence D. Daurio, Compliance Officer.

Sincerely,

Edward W. Thomas
Acting District Director